UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, and WISCONSIN, the DISTRICT OF COLUMBIA, and the CITY OF CHICAGO, *ex rel*. OSWALD BILOTTA, Plaintiffs and Relator, -against- NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	**No. 11 Civ. 00071 (PGG)**

NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS RELATOR'S THIRD AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Novartis Pharmaceuticals Corporation ("NPC") respectfully submits this Memorandum of Law in support of its motion to dismiss the Third Amended Complaint ("Complaint" or "Third Amended Complaint") brought under the False Claims Act, 31 U.S.C. § 3729 et seq. ("FCA"), and similar state statutes, by relator Oswald Bilotta ("Relator" or "Bilotta")—an action in which the United States Government (the real party in interest) and the State of New York have partially intervened and separately filed complaints.

Relator, a former NPC sales representative, claims that NPC's sales and marketing of its cardiovascular drugs was a "massive fraud" involving a "kickback campaign" that resulted in the submission of unidentified "false" claims to federal healthcare programs in violation of the FCA. His Complaint contains broad and conclusory allegations, purporting to implicate numerous FDA-approved drugs and to cover a timespan of over a decade. However, once Relator's Complaint is stripped of those allegations that he lacks standing to bring in light of the Government's limited declination (see infra Section I), the FCA's first-to-file and public disclosure bars (see infra Section II) and the FCA's statute of limitations (see infra Section III), only one allegation remains: alleged off-label promotion of the drug Valturna. This sole remaining allegation is deficient and should be dismissed as a matter of law for the following reasons.

First, Relator's off-label promotion claims fail under Rule 12(b)(6) because Relator does not plausibly allege: (1) how any claim submitted to a government healthcare program seeking reimbursement was false or fraudulent—the sine qua non of an FCA cause of action or (2) how NPC's alleged conduct caused prescribers of NPC's products, who are presumed to be exercising independent medical judgment, to submit false or fraudulent claims. (See infra Section IV.A.)

Second, Relator's Complaint is deficient under Rule 9(b) because his allegations lack the required specificity. Among other things, the Complaint does not plead with particularity the details of a single alleged false claim, link actual false claims to NPC's alleged wrongdoing or plead with particularity the details of the underlying fraudulent scheme. (See infra Section IV.B.)

In addition, for all the above reasons, the Court should dismiss Relator's state law claims or, alternatively, decline to exercise supplemental jurisdiction. (See infra Section V.)

FACTUAL BACKGROUND[1]

I. THE PRODUCTS AT ISSUE.

NPC is a pharmaceutical company that develops, manufactures and markets a broad portfolio of drugs. The allegations in Relator's Complaint pertain to drugs that were marketed by NPC's Cardiovascular ("CV") Division, including: Diovan, approved by the FDA in 1997 for the treatment of adult hypertension; Exforge, approved in June 2007 for the treatment of hypertension; Tekturna, approved in March 2007 for the treatment of hypertension;[2] Lotrel, approved in 1995 for the treatment of hypertension; Valturna, approved in September 2009 for the treatment of hypertension; and Starlix, approved in December 2000 for the management of Type 2 diabetes mellitus.

[1] For purposes of this motion, NPC must accept as true the allegations in the Complaint. Nothing in this memorandum of law, however, is intended or should be construed as an admission by NPC of any of the alleged conduct.

[2] Diovan, Exforge and Tekturna are also available in an "HCT" (hydrochlorothiazide) formulation. The HCT versions of the drugs contain an added diuretic, or "water pill".

II. THE EDPA INVESTIGATION AND SETTLEMENT.

A. The EDPA Investigation and the Earlier-Filed Garrity Qui Tam Action.

On September 30, 2010, the Department of Justice ("DOJ") announced that it had reached a settlement with NPC (the "EDPA Settlement") regarding an investigation conducted by the United States Attorney's Office for the Eastern District of Pennsylvania. On the same day that the EDPA Settlement was publicly announced, four related qui tam complaints were unsealed. One of them, filed by relator Jeremy Garrity (the "Garrity Complaint"), who was represented by the same counsel who represents Bilotta here, alleged "unlawful promotional practices" by the CV Division of NPC—the very same division of NPC at issue in the complaints filed by the Government and Bilotta. (Garrity Cmpl. ¶ 5, attached as Exhibit B to the Declaration of Nina M. Dillon ("Dillon Decl.").) The Garrity Complaint alleged that NPC induced physicians to write prescriptions for Diovan, Exforge and Tekturna by paying them kickbacks "through a panoply of kickback schemes" including "hiring and paying physicians as 'consultants' as part of a Speakers Bureau". (Id.) The Garrity Complaint further alleged that NPC's CV Division promoted its drugs for off-label uses. (Id. ¶¶ 58-74.) The Garrity Complaint (originally filed in 2008) was dismissed by the Pennsylvania district court on August 2, 2011.

B. The Terms of the EDPA Settlement.

As one component of the EDPA Settlement, NPC agreed to pay $36.5 million to resolve civil claims that it paid illegal kickbacks to healthcare professionals to induce them to prescribe Diovan, Exforge and Tekturna (as well as two other NPC drugs not at issue here). On the day the EDPA Settlement was announced, the DOJ issued a press release, which stated, among other things, that:

> "The civil settlement resolves claims that NPC . . . paid illegal kickbacks to health care professionals through mechanisms such as speaker programs, advisory boards, entertainment, travel and meals

> to induce them to prescribe Trileptal, as well as Diovan, Zelnorm, Sandostatin, Exforge and Tekturna."

(Dillon Decl. Exh. C. at 2.)

The public settlement agreement executed in connection with the EDPA Settlement contained a release for "Covered Conduct," which the agreement defined as:

> "During the period January 1, 2002 to December 31, 2009, NPC provided illegal remuneration, through mechanisms such as speaker programs, advisory boards, and gifts (including entertainment, travel and meals), to health care professionals to induce them to promote and prescribe the drugs Diovan®, Zelnorm®, Sandostatin®, Exforge®, and Tekturna®, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). As a result of the foregoing conduct, NPC caused false or fraudulent claims to be submitted to or caused purchases by Medicaid, Medicare and the other Federal Health Care Programs."

(Dillon Decl. Exh. D ¶ G.2.) Among other statutory claims, the Government released all claims under the FCA for the "Covered Conduct". (Id. ¶ 3.)

III. THE PRESENT SUIT.

A. Bilotta's Qui Tam Action.

Relator's Original Complaint was filed on January 5, 2011—just three months after the EDPA Settlement was publicly announced, but seven months before the Garrity Complaint was dismissed. Like the Garrity Complaint, Bilotta's Original Complaint alleges that NPC committed a "massive fraud" in connection with the sales and marketing of its cardiovascular medications. The Original Complaint is hardly a model of clarity. As best as can be discerned, it alleges, among other things, that (1) NPC used various vehicles, including speaker programs, to provide kickbacks to healthcare providers to promote products in NPC's CV Division (Orig. Cmpl. ¶¶ 56-97); (2) NPC promoted Valturna off-label for treatment of hypertension in diabetic patients (id. ¶¶ 98-118); and (3) as a result of kickbacks, NPC falsely reported the "Best Price" and "Average Manufacturer Price" for these products (id. ¶ 119-128).

Bilotta alleges (both in the Original and the Third Amended Complaint) that the relevant time period for his claims is 1999 through the present. (Id. ¶ 11.) In addition, Bilotta purports to bring claims on behalf of a variety of states and municipalities. (Id. ¶¶ 136-480.)

Relator's Original Complaint only mentioned Lotrel, Starlix and Valturna and specifically noted that "the drugs at issue in this case were not part of the 2010 [EDPA] settlement." (Id. at 2) (emphasis in original). He subsequently amended his complaint, however, to include claims related to Diovan, Exforge, Tekturna and the HCT versions of these drugs. Subsequent to serving his second amended complaint on NPC, Relator sought NPC's permission to drop the pricing violation claims and, on July 9, 2013, filed the Third Amended Complaint, which only includes allegations that NPC paid kickbacks in connection with various CV products and promoted Valturna off label.

B. The Government's Complaint in Intervention.

The Government's Complaint in Intervention ("DOJ Complaint"), filed on April 26, 2013, alleges that NPC's CV Division paid kickbacks to healthcare providers in connection with speaker programs. The alleged kickbacks resulted in the purported submission of "thousands" of false claims in violation of the FCA. (DOJ Cmpl. ¶ 6.) The relevant time period covered by the DOJ Complaint is January 2002 through November 2011. (Id. ¶ 1.)[3]

In its Notice of Partial Intervention filed on April 19, 2013, the DOJ stated that it was intervening in Bilotta's qui tam suit as to his speaker program related kickback claims and that it was declining to intervene with respect to Bilotta's claims concerning off-label promotion

[3] NPC filed a motion to dismiss the Government's Amended Complaint in Intervention ("DOJ Amended Complaint") on October 24, 2013. On the same day, it filed a motion to dismiss the Complaint in Intervention of the State of New York. Every other state and city named in Relator's Complaint has declined to intervene in this matter.

of Valturna and improper price reporting. (4/19/13 Notice of Partial Int. of the U.S.) Rather than amend his complaint to assert only the Government's declined claims, Bilotta simply served his existing March 21, 2013 complaint on NPC.

At a July 18, 2013 premotion conference before this Court to discuss NPC's anticipated motion to dismiss the DOJ Complaint, the Court indicated that the DOJ Complaint may not survive a motion and offered the Government the chance to amend. The Government filed its amended complaint on August 26, 2013. In light of the Court's comments at the July 18, 2013 premotion conference concerning the sufficiency of the DOJ Complaint (which Bilotta's counsel attended), NPC's counsel asked Bilotta's counsel whether they intended to further amend the Complaint. Bilotta's counsel declined to do so.

ARGUMENT

I. RELATOR MAY PURSUE ONLY THOSE CLAIMS IN WHICH THE GOVERNMENT DECLINED TO INTERVENE.

Where the government partially intervenes in a qui tam action under the FCA, a relator may proceed only with those claims in which the government declined to intervene. 31 U.S.C. § 3730(b)(4)(B); see also United States ex rel. Feldman v. City of New York, 808 F. Supp. 2d 641, 648 (S.D.N.Y. 2011); United States ex rel. O'Keefe v. McDonnell Douglas Corp., 918 F. Supp. 1338, 1346-47 (E.D. Mo. 1996). Here, the Government's Notice of Partial Intervention states:

> "The United States is intervening with respect to the relator's claims that from January 2002 through at least November 2011, Novartis caused false claims to be submitted to federal health care programs by paying kickbacks to doctors in conjunction with its speaker programs to induce the doctors to write prescriptions for certain Novartis pharmaceutical products. The United States is declining to intervene with respect to relator's claims that Novartis allegedly (1) marketed and promoted Valturna for off-label uses, and (2) engaged in pricing violations that caused false claims to be submitted."

(4/19/13 Notice of Partial Int. of the U.S. (emphasis added).) In its July 17, 2013, correspondence to the Court regarding its request to move to sever Relator's extant Complaint, the Government made clear that it "intervened with respect to the AKS allegations of Relator's action," and that "[w]ith respect to the claims as to which the Government has intervened, the Government's Complaint supersedes the Relator's Complaint". (See 7/17/13 Ltr. from H. Wendel to J. Gardephe at 1-2 (citing Feldman, 808 F. Supp. 2d at 649).)

Thus, Relator may proceed only with allegations relating to off-label promotion of Valturna and pricing violations (a claim Relator has abandoned in his most recent Complaint). Because Relator's Complaint (served after the Government's Notice of Partial Intervention) contains claims that, as the Government explicitly states, have been superseded by the claims in the DOJ Complaint, Relator lacks standing to assert them, and they should be dismissed as a matter of law. See United States ex rel. Eisenstein v. City of New York, 556 U.S. 928, 932 (2009) (once the government intervenes as to a claim in a qui tam action, it is vested with the "primary responsibility for prosecuting the action"); United States ex rel. Nichols v. Omni H.C., Inc., No. 02-cv-0066, 2008 WL 906426, at *1, *4 (M.D. Ga. Mar. 31, 2008) (allowing relator to pursue his FCA action after partial government intervention only in regards to fraudulent activity in which the government explicitly declined to intervene); In re Pharm. Indus. Average Wholesale Price Litig., 498 F. Supp. 2d 389, 397 (D. Mass. 2007) (where the government intervenes in a qui tam action, it has the right to amend relator's complaint with its own complaint in any way it chooses and relator cannot pursue any claims related to those being pursued by government).

II. THE KICKBACK ALLEGATIONS ARE ALSO BARRED UNDER THE FIRST-TO-FILE AND PUBLIC DISCLOSURE RULES.

Even if Relator could separately proceed with his superseded kickback claims (which he cannot), certain provisions of the FCA are specifically intended to prevent the Relator from proceeding with claims about which the Government is already on notice.

A. The FCA First-to-File Bar.

The FCA provides that "[w]hen a person brings an [FCA qui tam] action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action". 31 U.S.C. § 3730(b)(5). Under the first-to-file rule, once a relator brings a qui tam action alleging fraud under the FCA, all subsequent would-be relators are barred from bringing any claims based on the same set of material facts. United States ex rel. Smith v. Yale-New Haven Hosp., Inc., 411 F. Supp. 2d 64, 74-76 (D. Conn. 2005); United States ex rel. Capella v. United Techs. Corp., No. 94-cv-2063, 1999 WL 464536, at *9 (D. Conn. June 3, 1999); accord United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232-33 (3d Cir. 1998) ("[I]f a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details.") (emphasis added).[4]

The rationale for the FCA's first-to-file bar—which is "exception free"[5]—is that, because the first qui tam places the government on notice that it may have been defrauded, later suits alleging the same fraud serve no purpose. LaCorte, 149 F.3d at 234 ("[D]uplicative claims

[4] The FCA's first-to-file bar is jurisdictional and can accordingly be analyzed under Rule 12(b)(1) in addition to 12(b)(6). Capella, 1999 WL 464536, at *8.

[5] Smith, 411 F. Supp. 2d at 75; accord United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187 (9th Cir. 2001) ("[Section] 3730(b)(5)'s plain language does not contain exceptions.").

do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds."); accord United States ex rel. Batiste v. SLM Corp., 740 F. Supp. 2d 98, 105 n.3 (D.D.C. 2010) ("[O]nce the government is made sufficiently aware of the alleged fraud so that it can pursue its own investigation into the matter, little is gained by subsequent, duplicative claims from less-vigilant whistle-blowers."), aff'd, 659 F.3d 1204 (D.C. Cir. 2011).

Here, Relator's FCA claims are barred because the fraudulent scheme he alleges regarding NPC's marketing of its CV products overlaps with the fraud alleged in the previously filed Garrity Complaint. Indeed, as evident from Exhibit A to the Dillon Declaration, even a cursory comparison of the substantive allegations of the two complaints reveals striking (and, in some cases, verbatim) similarities.[6]

These "similarities" conclusively demonstrate that Garrity, not Bilotta, was the first person to allege the fraudulent scheme now resurrected in the Bilotta Complaint. Any additional details alleged by Bilotta cannot salvage his duplicative qui tam Complaint. See, e.g., LaCorte, 149 F.3d at 232-33 (fact that a subsequent qui tam adds details to a previously alleged fraud will not protect the later-filed complaint from dismissal); accord Smith, 411 F. Supp. 2d at 76-77 (dismissing later-filed suit under the first-to-file bar where the later complaint did no more than "flesh out the details of the particular fraud and the particular method").

Nor does the fact that Bilotta's Complaint contains allegations about additional NPC drugs save it from the first-to-file bar because the gravamen of the Garrity and Bilotta Complaints is identical: an allegedly fraudulent scheme by NPC's CV Division to pay kickbacks

[6] Even the typographical errors in the two complaints are the same. (See Dillon Decl. Exh. A at 5.)

to healthcare providers in order to increase prescriptions. See United States ex rel. Sandager v. Dell Mktg., L.P., 872 F. Supp. 2d 801, 807-08 (D. Minn. 2012) (dismissing later-filed complaint under first-to-file bar even where the computer equipment at issue differed because "the fraudulent scheme alleged [was] in material respects the same as the scheme alleged" in the earlier-filed complaint); United States ex rel. Folliard v. Synnex Corp., 798 F. Supp. 2d 66, 73 (D.D.C. 2011) (dismissing later-filed complaint alleging misrepresentations about the country of origin of Cisco products as barred by earlier-filed complaint alleging misrepresentations about the country of origin of HP products because both complaints alleged the same essential fraudulent scheme of misrepresenting products' country of origin). Because Bilotta's subsequently-filed Complaint is based upon the same facts as the Garrity Complaint, it is barred under the first-to-file rule. See, e.g., Smith, 411 F. Supp. 2d at 76-77, Capella, 1999 WL 464536, at *9.

B. The FCA's Public Disclosure Bar.

Bilotta's kickback allegations are independently precluded by the public disclosure bar. The FCA, as amended, provides that:

> "(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed–
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information."

31 U.S.C. § 3730(e)(4)(A). The purpose of the public disclosure bar is to "stifl[e] parasitic lawsuits" that are "based on" information already known to the Government. Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson, 130 S. Ct. 1396, 1407 (2010).[7]

The bar applies even where a relator's allegations are not derived from the publicly disclosed allegations. United States ex rel. Kreindler & Kreindler v. United Techs. Corp., 985 F.2d 1148, 1158 (2d Cir. 1993). Rather, a relator's "complaint need only be 'supported by' or 'substantially similar to' the [publicly] disclosed allegations and transactions" to be deemed sufficiently "parasitic" to trigger the public disclosure bar. United States ex rel. Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506, 519 (3d Cir. 2007) (citation omitted). See also United States ex rel. Blundell v. Dialysis Clinic, Inc., No. 09-cv-0710, 2011 WL 167246, at *6 (N.D.N.Y. Jan. 19, 2011) ("The Second Circuit follows the majority view and has repeatedly held that the relator's claim is 'based upon' the public disclosure if the allegations in the complaint are 'substantially similar' to the publicly disclosed information.").

Thus, the FCA's public disclosure bar applies even where the prior public disclosures do not identify the precise theory of fraud that the relator later alleges, but nonetheless contain "material elements of the 'allegations or transactions' on which the [fraud] claim is based". United States ex rel. Kirk v. Schindler Elevator Corp., 601 F.3d 94, 103 (2d Cir. 2009) (citing 31 U.S.C. § 3730(e)(4)(A)), rev'd on other grounds, 131 S. Ct. 1885 (2011); see

[7] Although some courts no longer consider the public disclosure bar to be jurisdictional (in light of the 2010 PPACA amendments), the public disclosure bar still "provides a basis for dismissal" under Rule 12(b)(6) and the Court may consider "judicially-noticeable public disclosures", such as a prior lawsuit and press coverage. United States ex rel. Chen v. EMSL Analytical, Inc., No. 10-cv-7504, --- F. Supp. 2d ---, 2013 WL 4441509, at *9 (S.D.N.Y. Aug. 16, 2013). Here, any potential argument against the Court's consideration of the Garrity Complaint and DOJ settlement is further foreclosed by Relator's own reference to them in his Complaint. (Cmpl. ¶¶ 7, 106.)

also United States ex rel. Kirk v. Schindler Elevator Corp., 437 F. App'x 13, 17 (2d Cir. 2011); United States ex rel. Woods v. Empire Blue Cross & Blue Shield, No. 99-cv-4968, 2002 WL 1905899, at *7 (S.D.N.Y. Aug. 19, 2002) (noting that public disclosures must raise only an inference, not necessarily demonstrate, the existence of fraud). Stated differently, where an FCA complaint relates to the "same fraudulent scheme" already disclosed, the public disclosure bar is triggered, even if the complaint "add[s] some color" to the fraud allegations already identified in the public disclosure. United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 115 (1st Cir. 2010); accord Woods, 2002 WL 1905899, at *7 ("The fact that those readers or listeners were not made aware of every possible detail of the fraud . . . is irrelevant.").

As described below, allegations substantially similar to Relator's kickback claims had already been publicly disclosed before Relator filed the instant action in January 2011.

1. Prior Public Disclosure of Allegations That NPC Paid Kickbacks.

As discussed supra Section II.A, a comparison of the Complaint to the previously filed Garrity Complaint, which was unsealed and made public in September 2010, exposes Bilotta's Complaint as a paradigmatic example of the type of "parasitic" action that the public disclosure bar was intended to prevent.[8] The scheme alleged by Garrity in 2008—that NPC's CV division directed the payment of kickbacks in order to induce prescriptions—is the same scheme alleged by Relator here. Indeed, the Garrity Complaint not only alleged the same general theory of fraud as Bilotta does here, it also contained many of the very same details of the alleged fraud—including describing the same mechanisms by which NPC allegedly paid

[8] In the Second Circuit, disclosure of information through unsealed court documents, as is the case here with the Garrity Complaint, is sufficient to invoke the public disclosure bar. See Kreindler, 985 F.2d at 1157-58.

kickbacks (e.g., through speaker programs, PILS programs and roundtables.) (See Dillon Decl. Exh. A.)

2. Additional Disclosures in the News Media.

Disclosures in the "news media" are also public disclosures. See 31 U.S.C. § 3730(e)(4)(A); see also United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc., 186 F. Supp. 2d. 458, 461 (S.D.N.Y.), aff'd, 53 F. App'x 153 (2d Cir. 2002). In September 2010, the DOJ issued a press release in connection with the EDPA Settlement. The press release explicitly referred to resolution of "claims that NPC . . . paid illegal kickbacks to health care professionals through mechanisms such as speaker programs" to induce them to prescribe certain of NPC's CV products. (Dillon Decl. Exh. C at 2.) As these prior public disclosures illustrate, Relator is not a true whistleblower because his claims against NPC bring no new information to the attention of the Government that was not already in the public domain. Not only were the essential elements of Relator's kickback claims disclosed publicly before he filed suit, but the very manner of how NPC allegedly accomplished these purported "schemes" was already in the public domain.

As with the first-to-file bar, Relator cannot avoid the FCA's public disclosure bar by simply providing additional details regarding NPC's previously disclosed alleged misconduct; nor can the public disclosure bar be circumvented by recasting public disclosures in different language. See, e.g., United States ex rel. Pritsker v. Sodexho, Inc., No. 03-cv-6003, 2009 WL 579380, at *9 (E.D. Pa. Mar. 6, 2009) (holding that a relator cannot "bypass public disclosures through the semantic legerdemain of recasting disclosed regulatory violations in false claims language"), aff'd, 364 F. App'x 787 (3d Cir. 2010); see also United States ex rel. Dingle v. Bioport Corp., 388 F.3d 209, 215 (6th Cir. 2004) (holding relators cannot "avoid the public

disclosure bar by pleading their complaints with more and more detailed factual allegations slightly different from more general allegations already publicly disclosed").[9]

3. Relator is Not an Original Source.

As a result of the foregoing public disclosures, Relator's Complaint must be dismissed unless he can establish that he is an "original source" who either:

> "(i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section."

31 U.S.C. § 3730(e)(4)(B). Relator bears the burden of establishing that he is an original source. United States ex rel. Assocs. Against Outlier Fraud v. Huron Consulting Grp., 843 F. Supp. 2d 464, 468 (S.D.N.Y. 2012). Relator's Complaint does not allege that he disclosed to the Government the information upon which his Complaint is based prior to the public disclosure of that information: the unsealing of the Garrity Complaint or the DOJ press release. Thus, the first "basis for original source status is simply not met." Chen, 2013 WL 4441509, at *14.

Therefore, Relator must demonstrate that he had knowledge that is both independent of and materially adds to the publicly disclosed allegations, which he also fails to do. Relator's kickback allegations are not "qualitatively different" from those previously alleged

[9] See also Chen, 2013 WL 4441509, at *13. Chen held that the public disclosure bar was implicated by a previous case even though the present case involved different defendants—companies that were wholly unique and unrelated to the defendants in the first case. Because the companies in both cases were part of the same industry (asbestos air testing), the court found that "[i]t is simply not plausible that government officials conducting an investigation into the frauds carried out by [the two defendants in the previous case] were not alerted by the information uncovered during those investigations to the prospect of wrongdoing by Defendants in this case." Id.

in the Garrity Complaint and DOJ press release, nor do they provide "some additional compelling fact" or demonstrate "a new and undisclosed relationship between the disclosed facts". See United States ex rel. Lockey v. City of Dallas, No. 11-cv-0354, 2013 WL 268371, at *16 (N.D. Tex. Jan. 23, 2013) (finding that relators' new information did not materially add to prior disclosures because the new information was not "qualitatively different"; was "merely the product and outgrowth of publicly disclosed" information; did not provide "some additional compelling fact"; and did not demonstrate "a new and undisclosed relationship between the disclosed facts") (citations omitted); United States ex rel. Osheroff v. Humana, Inc., No. 10-cv-24486, 2012 WL 4479072, at *12 (S.D. Fla. Sept. 28, 2012) (finding that relator's addition of details, including the value of meals provided to clinic patients and the number of passengers given free transportation, did not materially add to the information already publicly disclosed regarding the alleged kickback-based fraud).

III. RELATOR'S CLAIMS PRIOR TO JANUARY 2005 ARE BARRED BY THE STATUTE OF LIMITATIONS.

Relator purports to assert claims for alleged FCA violations dating from 1999 through the present. The FCA provides, however, that a relator may not bring an action "more than 6 years after the date on which the violation of [the FCA] is committed". 31 U.S.C. § 3731(b)(1); see also United States ex rel. Finney v. Nextwave Telecom, Inc., 337 B.R. 479, 485-86 (S.D.N.Y. 2006). Accordingly, all of Relator's claims based on alleged violations prior to January 2005 (or six years prior to the time he filed his Original Complaint) are time-barred and should be dismissed.

IV. RELATOR'S CLAIMS RELATED TO ALLEGED OFF-LABEL PROMOTION OF VALTURNA SHOULD BE DISMISSED.

A. Relator's Off-Label Allegations Fail Under Rule 12(b)(6).

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'". Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "'Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.'" Bigio v. Coca-Cola Co., 675 F.3d 163, 173 (2d Cir. 2012) (quoting Iqbal, 129 S. Ct. at 1949). Furthermore, in the context of fraud claims, Second Circuit case law makes clear that plaintiffs must allege facts that give rise to a "strong inference" of fraudulent intent. United States ex rel. Mooney v. Americare, Inc., 06-cv-1806, 2013 WL 1346022, at *3 (E.D.N.Y. Apr. 3, 2013).

To state a claim under 31 U.S.C. § 3729(a)(1)(A), Relator must allege that NPC "knowingly present[ed], or caus[ed] to be presented, a false or fraudulent claim for payment or approval". See United States ex rel. Feldman v. van Gorp, 697 F.3d 78, 86 (2d Cir. 2012) (citing 31 U.S.C. § 3729(a)(1)(A)). To state a claim under 31 U.S.C. § 3729(a)(1)(B), Relator must allege that NPC "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim". United States ex rel. Colucci v. Beth Israel Med. Ctr., 785 F. Supp. 2d 303, 310 (S.D.N.Y. 2011) (citing 31 U.S.C. § 3729(a)(1)(B)).

The FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment'". United States ex rel. Polansky v. Pfizer, Inc., No. 04-cv-0704, 2009 WL 1456582, at *5 (E.D.N.Y. May 22, 2009) (quoting United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995)). A claim is false or

fraudulent if it "'is aimed at extracting money the government otherwise would not have paid'". Colucci, 785 F. Supp. 2d at 310 (quoting Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001)).

Relator's off-label promotion allegations, which are limited to Valturna (see, e.g., Cmpl. ¶¶ 104-124), do not state a plausible claim for relief under the FCA for two independent reasons. First, Relator fails to plausibly allege how any claims submitted to government healthcare programs for reimbursement of Valturna prescriptions were "false or fraudulent"; Second, Relator does not allege that NPC "caused" the submission of any false claims for Valturna.

To state a claim under the FCA, Relator must sufficiently allege that NPC caused a medical provider to submit a "false"—i.e., non-reimbursable—claim to the government. As the government itself has conceded, "the core question for 'falsity' under the FCA is whether the government received a bill from a healthcare provider for an item or service that was not legally reimbursable". (United States' Statement of Interest in Resp. to Def.'s Mot. to Dismiss Counts I and III Through XIX of the Fifth Am. Cmpl. at 5, Polansky, No. 04-cv-0704 (E.D.N.Y. Sept. 24, 2010) (Dillon Decl. Exh. E).) Here, there is no dispute that Valturna was approved by the FDA for the treatment of hypertension. Relator alleges that NPC promoted Valturna for the treatment of hypertension in a sub-population of diabetic patients. The problem with Relator's theory, however, is that, even if true, it resulted only in on-label prescriptions. The FDA-approved indication for Valturna is "for the treatment of hypertension." (Cmpl. ¶ 54.) Relator's allegation that NPC marketed Valturna for the treatment of hypertension in diabetic patients (Cmpl. ¶ 108)

does not even plausibly allege off-label marketing of Valturna, let alone the submission of allegedly false claims.[10]

To demonstrate causation in the off-label marketing context, Relator must allege that: (1) NPC fraudulently promoted its drugs for off-label uses to doctors; (2) doctors submitted Medicare and Medicaid claims for off-label uses; and (3) these claims were a result of NPC's promotion of such off-label uses. See United States ex rel. Hess v. Sanofi-Synthelabo Inc., No. 05-cv-0570, 2006 WL 1064127, at *7 (E.D. Mo. Apr. 21, 2006). Relator's Complaint is deficient with respect to every link in this causal chain. He does not identify a single instance in which NPC promoted Valturna or any other drug to healthcare professionals for off-label uses or in which healthcare professionals submitted claims to the government for reimbursement for off-label uses. And, again, any prescriptions resulting from NPC's alleged off-label promotion would have been for hypertension—Valturna's FDA-approved indication.

Equally fatal to his claim, Relator does not allege that any doctor relied on any statement made by NPC regarding the off-label use of any NPC drug. Courts have consistently recognized that, as a general matter, doctors may prescribe drugs and medical devices for both FDA-approved and -unapproved uses. See, e.g., Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001). Mere conclusory allegations, such as those made by Relator here, are insufficient. See Segal v. Gordon, 467 F.2d 602, 607 (2d Cir. 1972) ("[T]here must be allegation of facts . . . amounting to deception in one form or another; conclusory allegations of deception

[10] Off-label promotion that results in a claim that is otherwise reimbursable is not actionable under the FCA. See United States ex rel. Rost v. Pfizer, Inc., 253 F.R.D. 11, 16-17 (D. Mass. 2008) ("Merely alleging off-label marketing . . . is not sufficient, without more, to plead a [F]alse [C]laims [A]ct violation"); Polansky, 2009 WL 1456582, at *6-7 (granting motion to dismiss and explaining that "the mere fact that Pfizer may have been violating FDA regulations does not translate into liability for causing a false claim to be filed").

or fraud will not suffice.") (citations and internal quotation marks omitted); Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004) (same).[11]

B. Relator's Off-Label Allegations Lack the Specificity Required Under Rule 9(b).

Relator's allegations of off-label marketing should separately be dismissed because they come nowhere near satisfying the particularity requirements of Rule 9(b). See Gold v. Morrison-Knudsen Co., 68 F.3d 1475, 1477 (2d Cir. 1995) (claims brought under the FCA are governed by the heightened pleading standard set forth in Rule 9(b)). In order to maintain an action under the FCA, Relator must (1) plead actual false claims with particularity; (2) link those actual false claims to NPC's wrongdoing; and (3) plead the underlying fraudulent scheme with particularity. Polansky, 2009 WL 1456582, at *5 (noting that pleadings that detail "[u]nderlying schemes and other wrongful activities that result in the submission of fraudulent claims" are "invariably . . . inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action") (quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004)); Chen, 2013 WL 4441509, at *18 ("[G]iven that . . . the Complaint does not provide any details as to the who, when or why of the false claims themselves, the precise manner in which Defendants' 'fake' samples and 'false' testing reports are linked to the 'false reports and invoices' allegedly submitted to the government

[11] Furthermore, Relator fails to rebut the presumption that doctors exercise their independent medical judgment in prescribing medication. See, e.g., Polansky, 2009 WL 1456582, at *6-7; see also Ironworkers Local Union 68 v. AstraZeneca Pharm., LP, 634 F.3d 1352, 1362 (11th Cir. 2011) ("[W]hen a doctor prescribes a drug, he presumably does so only if, in the exercise of his independent medical judgment, he believes the drug will benefit his patient."); UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 135 (2d Cir. 2010) ("The nature of prescriptions . . . means that [plaintiff's] theory of causation is interrupted by the independent actions of prescribing physicians . . . ."). Nor does he identify a single doctor who relied on NPC's alleged off-label promotion.

remains unclear (not to mention what false statements those reports and invoices actually contained)."); Mooney, 2013 WL 1346022, at *3-4 (dismissing allegations on Rule 9(b) grounds because details about the fraudulent scheme were "vague and unconnected to specific claims"); United States ex rel. Smith v. N.Y. Presbyterian Hosp., No. 06-cv-4056, 2007 WL 2142312, at *6 (S.D.N.Y. July 18, 2007) ("Although [Relator] manages to sketch out the nature of that claim by generally stating the 'who, what, where, when and how' of his theory of fraud, he fails to provide sufficient detail about that theory or about any specific fraudulent claim.").

Here, Relator fails to meet any of these three requirements and, accordingly, the Complaint should be dismissed.

1. Relator Fails To Plead Actual False Claims.

Rule 9(b) requires "details that identify particular false claims for payment that were submitted to the government". Polansky, 2009 WL 1456582, at *4 (quoting Karvelas, 360 F.3d at 232-33) (internal quotation marks omitted); United States ex rel. Moore v. GlaxoSmithKline, LLC, No. 06-cv-6047, 2013 WL 6085125, at *5 (E.D.N.Y. Oct. 18, 2013) (dismissing complaint for failure to plead false claims with particularity). Relator does not identify a single false claim that was submitted to the government; instead, he assumes that false claims must have been submitted. (See, e.g., Cmpl. ¶¶ 120, 128.) This conclusory assumption does not satisfy Rule 9(b) and renders the Complaint defective. United States ex rel. Piacentile v. Novartis AG, No. 04-cv-4265, slip op. at 15 (E.D.N.Y. Feb. 7, 2010) ("[A] simple recital of government programs to which Plaintiffs merely believe Novartis-linked physicians submitted false claims—even alongside specific and detailed allegations of the supposed fraud—cannot be enough to sustain these FCA counts under Rule 9(b).") (Dillon Decl. Exh. F); United States ex rel. Smith v. Yale Univ., 415 F. Supp. 2d 58, 88 (D. Conn. 2006) (dismissing case involving "allegations of a general scheme of fraud that might have resulted in the submission of false

claims"); Wood ex rel. United States v. Applied Research Assocs., Inc., 328 F. App'x 744, 750 (2d Cir. 2009) (same).

Relator also fails to explain how any of the alleged off-label marketing is linked to any alleged false claim. See United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 458-59 (4th Cir. 2013) (affirming dismissal under Rule 9(b) in part where relator failed to allege that the defendant pharmaceutical company caused doctors to write prescriptions for off-label uses). Among other things, Relator does not provide any specific allegations with respect to NPC promotional materials actually causing a single doctor to write a prescription that she would not have otherwise written. See, e.g., Polansky, 2009 WL 1456582, at *6-7; Ironworkers Local Union 68, 634 F.3d at 1362; UFCW Local 1776, 620 F.3d at 135; see also supra at 19 n.11. Not surprisingly, Relator fails to allege that any doctor abandoned her medical judgment as a result of any NPC promotional material.

2. Relator Fails To Plead the Alleged Fraudulent Scheme with Particularity.

Relator also fails to plead adequate details concerning NPC's alleged "scheme" of off-label marketing. See Chen, 2013 WL 4441509, at *18 (dismissing complaint that lacked "details as to the who, when or why"); Blundell, 2011 WL 167246, at *11-12 (dismissing plaintiff's FCA claims for lack of particularity under Rule 9(b) because although plaintiff "provided the approximate year of alleged quality care violations" he "did not provide specific dates, the names of defendant's employees who treated the patients, what services were provided or how and by whom false claims were generated as a result of those services"). None of the allegations relating to off-label marketing specifies who allegedly participated in the scheme with NPC. As set forth above, Relator does not identify a single specific instance of off-label promotion by NPC to a particular physician.

Relator's off-label marketing allegations also lack sufficient details as to when and where the activities took place. The closest Relator comes to specifying a when and where is his allegation describing a "regional planning meeting" that was held at "the Islandia Marriott hotel in Islandia, N.Y." on or around September 9, 2010. (Cmpl. ¶ 111.) These allegations, however, relate to internal NPC meetings—they do not assert (let alone with specificity) when or where any NPC product was actually marketed to a physician for an off-label purpose, or that any promotional piece was ever shown to a healthcare provider. See United States ex rel. Vallejo v. Investronica, Inc., 2 F. Supp. 2d 330, 336 (W.D.N.Y. 1998) (finding allegations insufficient under Rule 9(b) in part because plaintiff failed to allege the specific dates on which false representations were made); Hess, 2006 WL 1064127, at *6 (dismissing complaint where the relator "[did] not plead the time or place of the allegedly false representations" regarding the drug that was promoted for off-label use).

Finally, Relator fails to allege how the alleged scheme was implemented. The Complaint fails to assert, let alone with particularity, that NPC's senior management (or even a small group of lower-level employees) could or would have instituted a company-wide scheme to defraud the government. Relator's Complaint does not demonstrate a strong inference of fraudulent intent to violate the FCA (let alone on a national level), rendering it deficient. Cf. Wood, 328 F. App'x. at 747-48.[12]

[12] In addition to the numerous threshold issues that subject Relator's kickback claims to dismissal (see supra Sections II and III), the kickback claims also fail for the same reasons that Relator's off-label claims fail. Most glaringly, the kickback allegations do not satisfy the particularity requirements of Rule 9(b): they (1) fail to provide sufficient particularity regarding the who, what, when, where and how of the alleged kickback scheme; (2) fail to allege even one false claim resulting from an alleged kickback; and (3) fail sufficiently to allege conduct from which to reasonably extrapolate fraudulent activity in 31 different states and cities. See, e.g.,

V. RELATOR'S STATE LAW CLAIMS SHOULD BE DISMISSED.

A. Relator's State Law Claims Should Be Dismissed Because They Fail for the Same Reasons His Federal FCA Claims Fail.

In Counts II through XXXII, Relator alleges violations of false claims statutes of 31 different states and cities. All these statutes are substantively similar to the FCA—indeed, many track the language of the FCA. (Cmpl. ¶¶ 133-480.) For the same reasons discussed above in Sections I through IV, which are expressly incorporated here, Relator's state law claims should be dismissed.[13] See United States ex rel. Colquitt v. Abbott Labs., 864 F. Supp. 2d 499, 537 (N.D. Tex. 2012) (dismissing claims under state false claims and anti-kickback statutes and observing that public disclosure bars in the state statutes and FCA are "substantively identical"); United States ex rel. Conrad v. Grifols Biologicals Inc., No. 07-cv-3176, 2010 WL 2733321, at *6 (D. Md. July 9, 2010) (dismissing claims under 17 state false claims statutes where the allegations supporting those claims were insufficient to support claims under the FCA).

B. The Court Should Decline To Exercise Supplemental Jurisdiction.

The Court should also dismiss Relator's state law claims if the Court dismisses Relator's Federal FCA claim because there is no basis for exercising supplemental jurisdiction. See Brzak v. United Nations, 597 F.3d 107, 113-114 (2d Cir. 2010) ("[I]f a plaintiff's federal claims are dismissed before trial, the state claims should be dismissed as well.") (citation and internal quotation marks omitted); see also United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., No. 09-cv-1086, 2011 WL 3911095, at *6 (E.D. Va. Sept. 6, 2011) (dismissing FCA

Piacentile, No. 04-cv-4265, at 18-19 (dismissing FCA claim under Rule 9(b) for failure to sufficiently plead predicate AKS violations) (Dillon Decl. Exh. F).

[13] Relator's various state law claims should be dismissed for additional reasons specific to each state statute. NPC will raise these state-specific grounds for dismissal, if necessary, at the appropriate time.

claims and declining to exercise supplemental jurisdiction over state law claims), aff'd, 707 F. 3d 451 (4th Cir. 2013).

CONCLUSION

For the foregoing reasons, the Court should grant NPC's motion to dismiss and dismiss Relator's Complaint, in its entirety, with prejudice.

Dated: December 20, 2013

Respectfully submitted,

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